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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/518,753

06/30/2005

Joanne J. Fillatti

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EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT

PAPER NUMBER

1638

MAIL DATE

DELIVERY MODE

02/27/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/518,753	Applicant(s) FILLATTI, JOANNE J.	
	Examiner Elizabeth F. McElwain	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 1,2 and 15-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-14,20 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/17/05;2/8/07;8/13/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group V and SEQ ID NO: 1 in the reply filed on November 30, 2007 is acknowledged.

Claims 20 and 21 are newly submitted and will be examined with the elected group.

Claims 3-14, 20 and 21 are drawn to the elected invention and are examined on the merits.

Specification

1. The disclosure is objected to because of the following informalities: the first paragraph of the specification must be updated to indicate the present status of the parent application, which is now abandoned.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 3-14, 20 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 13, and claims 4-12, 14, 20 and 21 dependent thereon, are indefinite in the recitation of "complements thereof, and fragments of either" with regard SEQ ID NO: 1, since it encompasses a nucleic acid which is a combination of complements

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and/or fragments, wherein the complement or fragment may be any size and the nucleic acid may comprise any number of fragments and/or complements.

Claims 10 and 14 are indefinite in the recitation of “partially unaffected” since it is unclear how this would be interpreted and therefore the metes and bounds of the claims remain unclear.

Claims 11 and 14 are indefinite in the recitation of “substantially unaffected” since it is unclear how this would be interpreted and therefore the metes and bounds of the claims remain unclear.

Claim 14 is indefinite in the recitation of “essentially unaffected” since it is unclear how this would be interpreted and therefore the metes and bounds of the claims remain unclear.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 3-14, 20 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are drawn to a transformed soybean plant having a nucleic acid with 85% or greater identity to SEQ

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ID NO: 1, and complements and fragments thereof, wherein said soybean plant produces seeds having increased oleic acid, including 60-80% oleic acid.

However, the specification only describes SEQ ID NO: 1 as the FAD2-1A intron 1, and preparing a construct with a sense and antisense adjacent in the construct so that dsRNA is formed upon transcription (see Table II at pages 64-65). However, the specification does not teach a soybean plant transformed with any of the constructs set forth in the table much less any of the constructs encompassed by the claims, which include sequences that have greater than 85% identity to SEQ ID NO: 1, and complements and fragments thereof. The specification does not exemplify any plants encompassed by the claims, and it is unclear what the resultant phenotypes would be of a soybean plant transformed with any of the claimed constructs. Moreover, the specification does not disclose any soybean plants with seeds having increased oleic acid. Also, the specification does not disclose any soybean plants having selective reduction of the level of a transcript encoded by FAD2-1, while leaving the level of the transcript encoded by FAD2-2 partially, substantially or essentially unaffected. Furthermore, the specification fails to provide guidance with regard to how to choose from the multitude of sequences encompassed by the claims, and how any given transformant would be evaluated

Lee et al (Plant Physiology 119: 989-1000, 1999 in IDS) teach the unpredictability of modifying plant gene expression using sequences that are not identical to the endogenous sequences. Lee et al teach that an antisense RNA having 97% identity that does not inhibit expression of the endogenous gene (pp 993-994). Therefore, the modification of plant lipid composition or any other phenotypic change by transforming a plant with any of the nucleic acids encompassed by the claims is highly unpredictable.

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Thus, given the unpredictability of the effect of transforming a plant with a nucleotide sequence, as evidenced by Lee et al; and the lack of guidance in the specification for choosing a construct from the multitude that are claimed that will modify plant phenotype, and the lack of guidance with regard to how said transformed plant would be evaluated; the lack of working examples of nucleic acid constructs and their effect when transformed into a plant; and the breadth of the claims that encompass a multitude of possible sequence combinations, and use of said genes to modify fatty acid content in a plant; it would require undue experimentation by one skilled in the art to make and use the invention.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EFM

/Elizabeth F. McElwain/

Primary Examiner, Art Unit 1638